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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
RAO, MANJUNATH N	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 02/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/917,384	ADNEY ET AL.	
	Examiner	Art Unit	
	Manjunath N. Rao, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,14-35,44,45 and 69-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-11,14-25,28-35,44,45 and 69-74* is/are rejected.

7)☒ Claim(s) *4,5,26 and 27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ~~10~~ 9.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-11, 14-35, 44-45, 69-74 are still at issue and are present for examination.

Election/Restrictions

Applicant's election of Group I in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement and also cancelled all non-elected claims, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Drawings

Drawings submitted in this application are accepted by the Examiner for examination purposes only.

Claim Objections

Claims 4 and 5 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 4 and 5 have not been further treated on the merits.

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 24-73 have been renumbered as 25-74. Accordingly renumbered claims 36-43 and 46-68 have been cancelled as opposed to cancellation of claims 35-42 and 45-67 requested by applicants in paper No. 10, filed 8-2-02.

Claims 26 and 27 are objected to because of the following informalities: Claims 26 and 27 depend from a cancelled claim, claim 13. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 6-11, 14-35, 44-45, 69-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-3, 6-11, 14-35, 44-45, 69-74 are directed to compositions comprising a thermostable Gux1 peptide catalytic domain GH48. However, it is not clear to the Examiner as to what applicants specifically mean by "catalytic domain GH48" and what is the specific function of such a peptide. Also not clear to the Examiner is the catalytic property of the peptide. Examiner requests expansion of the abbreviation "GH" as well.

Claim 1 and claims 2-3, 6-11, 14-35, 44-45, 69-74 dependent from claim 1, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is directed to a composition comprising a "substantially purified" thermostable Gux1 peptide. The

metes and bounds of the phrase "substantially purified" is not clear to the Examiner. A perusal of the specification did not provide a specific definition for the above phrase. It is not clear to the Examiner as to what level of purity is considered as "substantially purified" by the applicants. Without a specific numerical value (i.e., percentage points) attached to the phrase, the above claim is rendered indefinite.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 is directed to a peptide as having a sequence of SEQ I DNO:2. However, SEQ ID NO:2 is a polynucleotide sequence and it is not clear to the Examiner as to how a peptide can have a polynucleotide sequence.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 is drawn to a composition comprising a sequence of SEQ ID NO:4, 5 and 7. It is not clear to the Examiner as to whether these sequences exist as linked to each other in the composition or exist as individual sequences, in the form of a mixture, in the said composition, rendering the claim indefinite.

Claims 14-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 14 to 21 are drawn to composition comprising Gux1 which is "further

defined as comprising nucleic acid sequence having....". It is not clear to the Examiner as to why a composition comprising a peptide, further comprises a nucleic acid encoding the same peptide or a portion of it. The claim at best is confusing, because the reason for combining a peptide and its encoding nucleic acid sequence is not clear to the Examiner. Also not clear is the function of such polynucleotide sequences in such compositions. Examiner has concluded that applicants intended to recite "as further comprising an amino acid sequence *encoded* by a nucleic acid sequence....." as opposed to the current recitation in the claim. For all further examination of the above claims Examiner has concluded as above.

Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 35 recites the limitation "the agent" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 44-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 44 and 45 recite the term "carrier". It is not clear to the Examiner as to what type of "carrier" applicants are referring to rendering the claims unclear.

Claims 1-3, 6-8, 22-25, 69-74 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-3, 6-8, 22-25, 69-74 are directed to composition comprising a Gux1 thermostable peptide wherein said Gux1 peptide comprises a catalytic domain GH48, a carbohydrate binding domain CBD type III and a CBD type II and fusion polypeptides comprising the same. Claims 1-3, 6-8, 22-25, 69-74 are rejected under this section of 35 USC 112 because the claims are directed to a genus of polypeptides including modified polypeptide sequences, modified by at least one of deletion, addition, insertion and substitution of an amino acid residue that have not been disclosed in the specification. No description has been provided of the all the polypeptide sequences encompassed by the claim. No information, beyond the characterization of SEQ ID NO:1 or partial characterization of SEQID NO:4-7, has been provided by applicants which would indicate that they had possession of the claimed genus of all the polypeptides. The specification does not contain any disclosure of the structure of all the polypeptide sequences derived from SEQ ID NO:1, including fragments and variants within the scope of the claimed genus. The genus of polypeptides claimed is a large variable genus including peptides which can have a wide variety of structures. Therefore many structurally unrelated polypeptides are encompassed within the scope of these claims. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 14-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to composition comprising a genus of DNA molecules.

The specification does not contain any disclosure of the function of all DNA sequences that are 70, 80 or 90% identical to SEQ ID NO:1 or 4, 5, 6, 7 as the case may be. The genus of DNAs that comprise these above DNA molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a single species of each of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 28-35, 44-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 28-35, 44-45 are directed to composition comprising a Gux1 thermostable peptide wherein said Gux1 peptide comprises a catalytic domain GH48, a carbohydrate binding domain CBD type III and a CBD type II and fusion polypeptides comprising the same. Claims 1-3, 6-8, 22-25, 69-74 are rejected under this section of 35 USC 112 because the claims are directed to a genus of polypeptides including modified polypeptide sequences, modified by at least one of deletion, addition, insertion and substitution of an amino acid residue that have not been disclosed in the specification. No description has been provided of the all the polypeptide sequences encompassed by the claim. No information, beyond the characterization of SEQ ID NO:1 or partial characterization of SEQID NO:4-7, has been provided by applicants which would indicate that they had possession of the claimed genus of all the polypeptides. The specification does not contain any disclosure of the structure of all the polypeptide sequences derived from SEQ ID NO:1, including fragments and variants within the scope of the claimed genus. The genus of polypeptides claimed is a large variable genus including peptides which can have a wide variety of structures. Therefore many structurally unrelated polypeptides are encompassed within the scope of these claims. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art

cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 6-10, 14-25, 28-35, 44-45, 69-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zverlov et al. (Microbiology, 1998, Vol. 144:457-465, Ref. In IDS) and Tomme et al. (J. Chromatography, 1998, Vol. 715:283-296, Ref in IDS). Claims 1-3, 6-10, 14-25, 28-35, 44-45, 69-74 in this instant application are drawn to a composition comprising a substantially purified thermostable peptide comprising a catalytic domain GH48 of a glycoside hydrolase (i.e., the catalytic domain of a glycoside hydrolase belonging to family 48), a type III carbohydrate binding domain (CBD) and a type II CBD, wherein all these domains are linked and the entire further comprises a linker and a signal peptide, wherein the catalytic domain is about 637 to about 643 amino acids, defined as SEQ ID NO:5 or encoded by a nucleic acid that is 70%, 80% or 90% identical to the nucleic acid that encodes SEQ ID NO:5, wherein the type III CBD is defined as SEQ ID NO:4 or encoded by a nucleic acid that is 90% identical to the

nucleic acid encoding SEQ ID NO:4, type II CBD defined as SEQ ID NO:7 or encoded by a nucleic acid that is 90% identical to the nucleic acid encoding SEQ ID NO:7 or wherein the entire peptide has SEQ ID NO:1 or encoded by a nucleic acid that is 90% identical to the nucleic acid encoding SEQ ID NO:1, or wherein the peptide further comprises the amino acid sequence encoded by a nucleic acid having 90% identity to the nucleic acid encoding peptide with SEQ ID NO:6, wherein the composition wherein the catalytic domain further comprises a heterologous protein in frame with the peptide, wherein such heterologous peptides as defined as peptide tag such as 6-His, thioredoxin, hemagluttin, GST, OompA signal or a substrate targeting moiety, wherein the composition comprises amino acid sequences with SEQ ID NO:1, 4-7 or amino acid sequences that are 70%, 90% identical to SEQ ID NO:1, 4-7, a composition comprising a fusion protein comprising such peptides and a heterologous peptide wherein the heterologous peptide is a substrate targeting moiety such as peptide tag, 6-His, thioredoxin, hemagluttin, GST, OompA signal or wherein the heterologous peptide promotes polypeptide oligomerization, wherein the composition comprises a carrier, or an immunoglobulin.

Zverlov et al. teach a thermostable glucoside hydrolase enzyme comprising a catalytic domain GH48, a type III CBD and further comprising a signal peptide and a linker peptide. The reference teaches a method of obtaining such peptide sequence and provides the cloning strategy for the same along with techniques for manipulating such sequences (see entire reference specifically figure 4). However, the reference does not teach regarding such a peptide comprising an additional type II CBD or a composition comprising such a peptide as a fusion peptide with a heterologous peptide as described above.

Tomme et al. teach regarding the characterization and affinity application of different CBDs. The reference compares between different CBDs and extols the property of each type and also suggests as to how such CBDs can be used. The reference teaches that family II and III CBDs bin to cellulose irreversibly and such binding may be favorable for some type of applications. The reference also provides techniques for manipulating CBD and their sources.

Combining the teachings of the above two references, it would have been obvious to one of ordinary skill in the art to make a DNA construct comprising the peptide of Zverlov et al. further comprising an additional CBD such as the type II CBD taught by Tomme et al. Such construction of hybrid cellulose is well known in the art. Skilled artisans have genetically manipulated several types of cellulases with specific CBDs to suit a variety of applications. One of ordinary skill in the art would have been motivated to do so in order to make a thermostable cellulase capable of binding robustly and irreversibly to cellulose such that it is favorable for complete hydrolysis of the cellulose substrate. One of ordinary skill in the art would have a reasonable expectation of success since Zverlov et al. already provide such a peptide except for the additional CBD and Tomme et al. teach all the properties and applications of several types of CBD for picking and choosing any combination depending on the application.

Therefore the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art.

Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional

characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 7:30 a.m. to 4:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Manjunath N. Rao Ph.D.
Patent Examiner A.U. 1652
2/12/03